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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,410	09/07/2006	Calvin B. Harley	38797-8007.US00 (511/002)	6086
22869	7590	09/10/2009	EXAMINER	
GERON CORPORATION Attn. David J. Earp 230 CONSTITUTION DRIVE MENLO PARK, CA 94025			LOVE, TREVOR M	
			ART UNIT	PAPER NUMBER
			1611	
			MAIL DATE	DELIVERY MODE
			09/10/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/562,410	<b>Applicant(s)</b> HARLEY ET AL.	
	<b>Examiner</b> TREVOR M. LOVE	<b>Art Unit</b> 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 17-25 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-9 and 17-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/11/2009, 07/30/2009</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Acknowledgement is made to Applicant's response and IDS filed 03/11/2009 and IDS filed 07/30/2009.

Claims 1-10 and 17-25 are pending. Claims 4 and 10 stand withdrawn. Claims 1-3, 5-9, and 17-25 are currently under consideration.

Any rejection and/or objection not restated herein is to be considered withdrawn.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 1-3, 5-9, and 17-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mousa (U.S. Patent number 6,171,604) in view of Chou (U.S. Patent number 6,855,344) or Chou (U.S. Pre-Grant publication 2003/0108629) as evidenced by Papadopoulos et al (JAOCS), Close (U.S. Pre-Grant publication number 2002/0044977), and Wu (U.S. Patent number 6,696,094).**

Mousa teaches the application of honey for topical treatment of the skin, including skin infections (see Abstract and claim 3-5). In one preferred embodiment Mousa teaches that said composition comprises olive oil, glucose sesquiistearate, methyl glucose dioleate, and honey (see column 6, example 11). Olive oil is known to comprise antioxidants (see Papadopoulos, page 671, first column, first paragraph). Glucose sesquiistearate and methyl glucose dioleate are taught by Mousa to be

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emulsifiers (see column 5, lines 60-62). Honey is known to be an emulsifier in topical compositions (see Close, [0012]-[0013]).

Mousa fails to directly disclose that the composition comprises Applicant's elected species cycloastragenol, the amount in which said cycloastragenol is present, or that the composition has the particular telomerase activity or refluence under the instantly identified conditions.

Both Chou references teach a composition which can be topical which utilizes extract of Radix Astragali [Huangqi] (see Chou Patent, column 17, lines 31-43 and column 22, lines 1-5; see Chou PG-pub, [0150] and [0186]), wherein it is evidenced by Wu that a major ingredient of Radix Astragali is cycloastragenol (see Wu, column 6, Table 1). Said Radix Astragali is taught in Chou to be known for relieving skin infections (see Chou Patent, column 15, lines 25-39; see Chou PG-pub, [0135]-[0140]). It is further taught in Chou that in the composition of Chou Radix Astragali is present in an amount such that one of the major ingredients, astragaloside, is present in an amount of 0.365% (see Chou Patent, columns 18-19, Table III; see Chou PG-pub, [0156], Table III).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the extract of Radix Astragali in the invention of Mousa. One would have been motivated to utilize extract of Radix Astragali in the invention of Mousa since Radix Astragali is taught as being useful for the relieving of skin infections, and the composition of Mousa is also taught as being useful for skin infections. It is noted that MPEP 2144.05 states: "It is *prima facie* obvious to combine two

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compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.” *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960); and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992). There would be a reasonable expectation of success in the combination since Mousa and both Chou references are teaching compositions that are useful for treating skin infections.

With regard to the new limitation that the compound is isolated, it is noted that the Radix Astragali is taught in both Chou references as being useful in the extracted form. One would have been motivated to utilize the extracted form to allow for a more concentrated form of the active ingredients.

With regard to the amount of cycloastragenol present, though both Chou references are silent as to the amount of cycloastragenol which is preferred, both Chou references do teach a preferred amount of Astragaloside, specifically, 0.365%. Given that Astragaloside and cycloastragenol are both evidenced in Wu to be major ingredients of Radix Astragali, it is the position of the Examiner that the 0.365% would be a starting value which one of ordinary skill in the art would look to for the amount of cycloastragenol. Said amount would be readily optimized by adding more or less extracted Radix Astragali. It is noted that MPEP 2144.05 states: “In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976);

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*In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990); *In re Geisler*, 116 F.3d 1465, 1469-71, 43 USPQ2d 1362, 1365-66 (Fed. Cir. 1997). Also, it is further noted that MPEP 2144.05 states: “a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985)”.

With regard to the telomerase activity and refluence under the instantly identified conditions, it is the position of the Examiner that absent evidence to the contrary, the composition of Mousa as modified by either Chou reference would necessarily have the same telomerase activity and refluence when placed in the conditions instantly identified. Since the composition of Mousa in view of either Chou reference teaches similar if not the same components, it is the position of the Examiner that the properties of the composition would also be similar, if not the same. It is noted that MPEP 2112 states: “[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer.” *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).”

*Response to Arguments*

Applicant argues in the response filed 03/11/2009 that Chou (U.S. Pre-Grant publication 2003/0108629) fails to report cycloastragenol as a component of Radix Astragali. Applicant's argument is not found persuasive since, as can be seen above, reference Wu provides evidence that cycloastragenol is a major ingredient of Radix Astragali. Applicant further states that Chou teaches Radix Astragali is taught as treating a large variety of diseases, wherein the final composition of Chou is directed to treating the kidneys or prostate. Applicant's argument is not found persuasive since Chou clearly teaches that Radix Astragali relieves skin infection, and one of ordinary skill would have been motivated to utilize Radix Astragali given Mousa in view of Chou since both the composition of Mousa and Radix Astragali (as taught by Chou) are useful for skin infections. Applicant further argues that any one of the ingredients of Radix Astragali could have been responsible for the effects which treated one of the individual diseases. Applicant's argument is not found persuasive since given Mousa in light of Chou, one would have been motivated to utilize Radix Astragali, one would not necessarily need to know which component had which function. Applicant further argues that in Table III of Chou, Chou teaches that in the final product the astragaloside of Radix Astragali is not present in a detectable amount. Applicant's argument is not found persuasive since the final composition of Chou is not what reference Chou is being relied upon to teach, reference Chou provides motivation for one to desire the presence of Radix Astragali in the invention of Mousa. Applicant further argues that it would be unlikely that topical treatment would be effective for the treatment of the kidney or prostate. Applicant's arguments are not found persuasive since, as stated

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above, reference Chou is being relied upon for the teaching concerning Radix Astragali rather than the final product of Chou. Based on inhibition of cell growth that Applicant alleges is taught by Chou, Applicant argues that the composition of Chou teaches away from the instant invention, which is directed to skin conditioning. Applicant argues that the alleged cell growth inhibition and in some cases cell apoptosis of Chou shows that the telomerase activity and refluence are not necessarily present in the invention of Chou. Applicant's arguments are not found persuasive since there is no indication that the cell inhibition is in any way a resultant of Radix Astragali, wherein it is further noted that the telomerase activity and refluence are properties of the components which would necessarily be present.

### ***Conclusion***

No claims allowed. All claims rejected. No claims objected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TREVOR M. LOVE whose telephone number is (571)270-5259. The examiner can normally be reached on Monday-Thursday 7:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TL

/Gerald G Leffers Jr., PhD/  
Primary Examiner